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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,941	02/21/2006	Michael Horstmann	RO4150US (#90568)	7611

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,941	HORSTMANN ET AL.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-10 and 14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-21-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 2-4, 6-10, and 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 12, 2009.

Applicant's election with traverse of (b) the combination of L-dopa and an anticholinergically active substance (scopolamine) in the reply filed on November 12, 2009 is acknowledged. The traversal is on the ground(s) that the special technical feature of the invention is the variety of combinations is used to treat Parkinson's disease. This is not found persuasive because Applicant has claimed a transdermal device which may comprise a number of active agents to be used in various combinations. The claims are not drawn to methods of treating Parkinson's disease. Therefore, the future intended use of the device is not given patentable weight. There is not special technical feature amongst the numerous combinations.

The requirement is still deemed proper and is therefore made FINAL.

However, after further consideration of the election of species requirement for the anti-cholinergically active agent, the Examiner has withdrawn said requirement for an election.

Claims 1, 5, and 12-13 are therefore under prosecution in this application.

Priority

Applicant's claim of priority as a 371 of PCT/EP04/09136 filed on August 14, 2004 is acknowledged. Applicants claim of priority to German application 103 38 174.0 filed on August 20, 2003 is acknowledged. Certified copies of the foreign priority documents have been received, however, English translations are not of record.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on February 21, 2006 is acknowledged. A signed copy is attached to this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 13, Applicant also has not specifically set out if the at least two active agents are contained in different layers or compartments individually or together. Clarification to the claim language is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by El-Rashidy et al. (US Patent 6,193,992).

El-Rashidy discloses the administration of apomorphine (abstract). It is additoally disclosed the apomorphine can be administered in conjunction with a parasympathetic depressant, such as scopolamine (column 5, line 58 through column 6, line 5).

While it is acknowledged by the Examiner that El-Rashidy's exemplified embodiments are drawn to sublingual administration, he does disclose that the compositions can be formulated as transdermal devices (column 2, lines 45-48).

While the combination of apomorphine and scopolamine are not exemplified, the combination is presented in a finite grouping of agents; therefore, the skilled artisan would immediately envision their use together.

The recitation of "for treatment of Parkinson's Disease" is regarded as future intended use and therefore not given patentable weight in composition/device claims. Therefore, El-Rashidy's disclosure of the recited components used in combination for transdermal administration meets the limitations of the claims.

Claims 1, 5, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoenleber et al. (US Patent 4,963,568).

Schoenleber discloses compounds which are selective dopamine agonist useful for treating disorders characterized by abnormal dopamine levels, including Parkinson's disease (abstract).

It is additionally disclosed that L-Dopa (dihydroxyphenylalanine), when used in conjunction with a peripheral aromatic amino acid decarboxylase inhibitor, and often supplemented with anticholinergic agents, has been shown to be useful in the treatment of Parkinson's Disease (column 1, lines 37-45).

The compounds disclosed by Schoenleber are administered in conjunction with the L-Dopa and anticholinergic agents. (column 7, lines 12-15). Anti-cholinergic agents disclosed include benztropine, biperiden, ethopropanzine, procyclidine, trihexylpenidyl, and the like.

The composition can be administered as a transdermal patch (column 9, lines 64-68). The reference therefore meets the limitations of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, and12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US Patent 5,614,178).

Bloom discloses transdermal devices comprising an active agent (abstract). The agent can be selected from numerous classes of drugs, including anti-cholinergic drugs including scopolamine and levodopa (L-Dopa) (column 5, lines 50-55).

It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining

them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of anti-cholinergic drugs. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). It would have been obvious to the skilled artisan at the time the invention was made to have combined two known agents which are used for the same purpose into a transdermal device.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over El-Rashidy et al. (US Patent 6,193,992) in view of Reed Jr. (US Patent 4,877,618), or in the alternative, Schoenleber et al. (US patent 4,963,568) in view of Reed Jr. (US Patent 4,877,618).

The teachings of El-Rashidy and Schoenleber are individually discussed above and applied in the same manner.

Neither reference discloses the configuration of the transdermal device.

Reed discloses transdermal devices for drug delivery. The device comprises a plurality of adhesive laminae containing the drug to be transdermally delivered (abstract).

The skilled artisan would have a reasonable expectation of making a transdermal delivery device comprising multiple layers or reservoirs as recited in the instant claims since both El-Rashidy and Schoenleber disclose l-dopa and an anticholenergically active substance are suitable for transdermal administration. It would have been

obvious to one of ordinary skill in the art at the time the invention was made to have used the transdermal disclosed by Reed with the formulation disclosed by El-Rashidy and Schoenleber since Reed discloses the use of the drug being contained in multiple layers allows for an essentially constant, but somewhat declining, delivery rate of a drug from the contact adhesive to the adhered skin as the drug adsorbed in the interlaminar layers is depleted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615